

DETAILED ACTION

1. This office action is in response to the amendment filed 5/6/11. As directed by the amendment claims 1, 3, and 6 have been amended and claims 15-18 have been added. As such, claims 1-12 and 15-18 are pending in the instant application.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Note that the term "means" in line 2 is improper language for the abstract.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the heating means, chamber base/heat conductive base, electrical plug/socket, breathing circuit with complementary electrical and pneumatic connectors, and air bleed orifice must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "said humidification chamber" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

Also in regards to claim 4, it is not known which chamber is being referred to in the term "said chamber" in line 2, the humidification chamber or the water chamber.

Claim 8 recites the limitation "said filter means" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "the structural members" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 is rejected based upon dependency to a rejected claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-2 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenyon et al. (6,397,841) in view of Lipscombe et al. (6,554,260) and Clawson et al. (6,363,930).

In regards to claim 1, Kenyon shows an apparatus for use in humidified gases delivery (see Fig. 1 and 3 for example) which includes a housing 32, a pressurized gases supply 12 within the housing, a pressurized gases outlet 22 in the housing in fluid connection with the pressurized gases supply and adapted to make fluid connection with an inlet 25 of a humidifier 26 in order to provide pressurized gases flow to the humidifier (see Fig. 1 and 3 for example). Kenyon is silent as to providing a filter in the gases inlet of the humidifier and downstream of the pressurized gases supply; however, Lipscombe teaches a CPAP humidifier device which includes a filter in the gases inlet of a humidifier and downstream of a pressurized gases supply (see Lipscombe col. 4 ln. 27-31). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Kenyon device to include a filter in the gases inlet of the humidifier and downstream of the pressurized gases supply, as taught by Lipscombe, in order to reduce the presence of bacteria in the device. The now modified Kenyon device is silent as to the filter being removable; however, Clawson teaches a breathing device which includes a removable filter (see Clawson col. 2 ln. 56-59). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Kenyon device's filter to be removable, as taught by

Clawson, in order to ensure the filter is functioning properly and to replace the filter when necessary to prevent contamination.

In regards to claim 2, the modified Kenyon device includes a gases return (Kenyon 24) in the housing, adapted to make fluid connection with an outlet (Kenyon 28) of the humidifier in order to receive humidified gases from the humidifier, and a patient outlet (Kenyon 14) in the housing, in fluid connection with the humidified gases return in order to receive humidified gases from the humidified gases return and provide humidified gases to the patient outlet, the patient outlet being in fluid connection with or adapted to make fluid connection with a breathing circuit (Kenyon 16) for delivery of humidified gases to a patient.

In regards to claim 15, the modified Kenyon device's filter is positioned such that the filter can filter pressurized gases entering the humidifier and protect the pressurized gases supply and housing from contamination. Note that the filter in the inlet of the modified Kenyon device includes all the same structure such that it protects the supply and housing as claimed.

In regards to claim 16, the modified Kenyon device's filter is positioned such that the filter can filter pressurized gases entering the humidifier and protect the humidifier from contamination. Note that the filter in the inlet of the modified Kenyon device includes all the same structure such that it protects the humidifier as claimed.

7. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenyon et al. (6,397,841), Lipscombe et al. (6,554,260) and Clawson et al.

(6,363,930) as applied to claim 1 above, and further in view of Mayer et al. (7,096,864).

In regards to claim 3, the modified Kenyon device teaches all the limitations as discussed above, but is silent as to explicitly disclosing that the humidifier is a heatable water chamber and includes a chamber heating means connected to the housing, the chamber heating means adapted to vaporize liquid water in the water chamber in order to provide water vapor to the gases flow passing through the water chamber. However, Mayer teaches a CPAP/humidifier device which includes a heatable water chamber (Mayer 17, Fig. 1, col. 11 ln. 37) heated by a chamber heating means (see Mayer col. 3 ln. 58-59) connected to the housing and adapted to vaporize liquid water in the chamber in order to provide water vapor to the gases flow passing through the water chamber (see Mayer Fig. 1 and col. 12 ln. 49-50). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Kenyon device to use the heatable water chamber with chamber heating means humidifier, as taught by Mayer, in order to provide a humidifier that is "coupled directly laterally to a CPAP-unit easily and without the need for expert assembly procedures" (see Mayer col. 1 ln. 64-66). The now modified Kenyon device's heating means is connected to the housing as claimed as (see Fig. 1 of Kenyon and Mayer Fig. 1 and col. 12 ln. 33-36) and includes a humidifier engagement locating a humidifier adjacent the chamber heating means (see Kenyon Fig. 1 and Mayer Fig. 1 and col. 12 ln. 33-36).

In regards to claim 4, the modified Kenyon device's humidification chamber includes a base and the chamber is engagable with the humidifier engagement via a

single motion (see Mayer Fig. 1), and the single motion of engagement urges the base of the humidification chamber adjacent and in contact with the chamber heating means (see Mayer Fig. 1 and col. 12 ln. 33-36) and makes a first fluid connection between the pressurized gases outlet and the humidifier inlet, and makes a second fluid connection between the humidified gases return and the humidifier outlet, with the first and second fluid connections being made in the direction of the single motion (see Kenyon Fig. 1 and Mayer Fig. 1).

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kenyon et al. (6,397,841), Lipscombe et al. (6,554,260) and Clawson et al. (6,363,930) as applied to claim 2 above, and further in view of Blackhurst (WO 02/32486).

In regards to claim 5, the modified Kenyon device teaches all the limitations as discussed above, but is silent as to the patient outlet including a connector for receiving a breathing hose **and** at least one auxiliary electrical connection plug or socket or pneumatic connection plug or port, for a simultaneous connection with connecting a breathing circuit having complementary electrical and pneumatic connectors. However, Blackhurst teaches a breathing house with a connector (3 see Blackhurst Fig. 2) which also includes at least one auxiliary electrical connection plug or socket (Blackhurst Fig. 2 via connection 21 see also pg. 9 ln. 6-7) **or** pneumatic connection plug or port, for a simultaneous connection when connecting a breathing circuit having complementary electrical and pneumatic connectors (see Blackhurst Fig. 2; note that the breathing

conduit and electrical connection are both connected simultaneously). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Kenyon device to include the auxiliary electrical connection plug as claimed as taught by Blackhurst in order to provide the ability to further heat the gas via a breathing conduit heater element for example in order to maintain proper temperature and humidity level of the breathing gas being supplied to the patient.

9. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenyon et al. (6,397,841), Lipscombe et al. (6,554,260) and Clawson et al. (6,363,930) as applied to claim 1 above, and further in view of Hoffrichter (DE 10226160).

In regards to claim 17, the modified Kenyon device teaches all the limitations as discussed above, but is silent as to the humidifier explicitly having a water chamber with the removable filter being attached inside the water chamber. However Hoffrichter teaches a humidifier device which includes a water chamber with inlet/outlet tubes extending into the water chamber (see Hoffrichter Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Kenyon device's humidifier inlet/outlets to extend into a water chamber, as taught by Hoffrichter, in order to provide a smaller, more compact device (as opposed to the lengthy inlet/outlet tubes of Kenyon Fig. 1 or 3). The now modified Kenyon device teaches a humidifier water chamber with gases inlet extending into the chamber (see Hoffrichter Fig. 1) and a filter in the humidifier inlet (see Lipscombe col. 4 In. 28-31), and

it would have been obvious to one of ordinary skill in the art at the time the invention was made to place the filter such that it is inside the water chamber (humidifier gases inlet includes the filter and inlet as shown in Fig. 1 of Hoffrichter extends into the water chamber).

In regards to claim 18, the modified Kenyon device, as modified above in rejection of claim 17, includes a humidifier with a water chamber (see Fig. 1 of Hoffrichter) and the removable filter and water chamber are detachable from the pressurized gases supply together (see Kenyon Fig. 1-3, removable filter Lipscombe col. 4 ln. 28-31, and Hoffrichter Fig. 1).

10. Claims 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickinson et al. (6,398,197) in view of Lipscombe et al. (6,554,260) and Clawson et al. (6,363,930).

In regards to claim 6, Dickinson shows a humidifier chamber for use with a gases humidification apparatus which includes a container 4 with a surrounding wall and top, and an open bottom (see Fig. 2 and 3), a heat conductive base 6 enclosing the open bottom of the container (see Fig. 3 and col. 2 ln. 17), a gases inlet 2 to the container for receiving pressurized gases for humidification from any pressurized gases supply, a gases outlet 3 to the container. Dickinson is silent as to providing a filter in, on or over the gases inlet to the container and downstream to any pressurized gases supply, the filter positioned such that the filter can filter any pressurized gases to the container. However, Lipscombe teaches a CPAP humidifier device which includes a filter in the

gases inlet of a humidifier and downstream of a pressurized gases supply (see Lipscombe col. 4 ln. 27-31). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Dickinson device to include a filter in the gases inlet of the humidifier and downstream of the pressurized gases supply, as taught by Lipscombe, in order to reduce the presence of bacteria in the device. The now modified Dickinson device is silent as to the filter being removable; however, Clawson teaches a breathing device which includes a removable filter (see Clawson col. 2 ln. 56-59). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Dickinson device's filter to be removable, as taught by Clawson, in order to ensure the filter is functioning properly and to replace the filter when necessary to prevent contamination.

In regards to claim 12, the modified Dickinson device includes a cylindrical chamber (see Fig. 1 Dickinson) but is silent as to explicitly disclosing that the inlet and outlet ports are **both** a female port (note only inlet 2 Dickinson clearly shows female port). However, one of ordinary skill in the art at the time the invention was made would have found it obvious to choose the ports to be a female connection port (as opposed to a male connection port) as this is considered to be a matter of design choice. Furthermore one would expect the modified Dickinson's device to perform equally as well with the claimed both female ports. Note that the ports open out to the cylindrical surface adjacent the top of the cylinder wall.

11. Claims 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickinson et al. (6,398,197), Lipscombe et al. (6,554,260) and Clawson et al. (6,363,930) as applied to claim 6 above, and further in view of Hoffrichter (DE 10226160) and Kenyon et al. (6,397,841).

In regards to claim 7, the modified Dickinson device teaches all the limitations as discussed above including a first elongate flow tube extending into the humidifier container from the inner periphery of the gases inlet (7 Fig. 2 of Dickinson). However, the modified Dickinson device is silent as to including a second elongate flow tube extending into said humidifier container from the inner periphery of said gases outlet. Hoffrichter teaches an air humidifier for a respirator which includes a tube extending into the humidification chamber from the inner periphery as claimed. (18 of outlet 9; Fig. 4 Hoffrichter) The two flow tubes taught by Hoffrichter are also substantially parallel to each other, and substantially parallel to said base of said chamber. (See Fig. 4 Hoffrichter) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the gases outlet of the modified Dickinson's device to include a parallel tube extending into the humidification chamber in view of Hoffrichter, because Hoffrichter states that this allows "the air current mixes with the steam without resistance, yet prevents water from flowing back" (Abstract Hoffrichter). The now modified Dickinson's device is silent as to having said gases inlet and said gases outlet facing the same direction, a preferred insertion direction, and said preferred insertion direction is substantially parallel to the said base of said chamber, such that said humidifier chamber may make operable engagement with a heater base in a single

motion, and fluid connections with said gases outlet and said gases inlet, being also made in said single motion. Kenyon teaches a humidification apparatus where the gases inlet and outlet are facing the same direction and parallel to the base. (See Fig. 3 Kenyon) The inlet and outlet tubes are also parallel to the single motion engagement direction which make fluid connections during engagement. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the modified device of Dickinson to have the gases inlet and outlets configured in view of Kenyon, because Kenyon states that the engagement setup advantageously allows "the apparatus can be quickly and easily converted between including, or not including, a humidifier in the gas supply path" (col. 4 ln. 10).

In regards to claim 11, the modified Dickinson's device is silent as to the second flow tube including an air bleed orifice. However, Kenyon teaches a humidifier device which includes an air bleed orifice (64 Fig. 6 Kenyon) on top of a flow tube. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Dickinson's device's second flow tube to include an air bleed orifice, as taught by Kenyon, in order to provide a port in which sensors/transducers can monitor the activity of the device (see Kenyon col. 4 ln. 44-50).

12. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickinson et al. (6,398,197), Lipscombe et al. (6,554,260) and Clawson et al. (6,363,930) as applied to claim 6 above, and further in view of Kurashima (6,033,455) and Fukunaga et al. (2002/0017302).

In regards to claims 8 and 10, the modified Dickinson device teaches all the limitations as discussed above, but is silent as to the filter including a framework substantially supporting a filter material and being shaped to fit an internal shape of the inlet. However, Kurashima teaches a filter which includes a framework (Kurashima 1 and 2 see Fig. 3 for example) supporting a filter material (Kurashima 15 see Fig. 3 for example) where the framework is shaped to fit the internal shape of the inlet (see Kurashima Fig. 1 and 6 for example; note that inlet/outlets of the framework are sized to fit with a breathing conduit; see also Kurashima col. 6 ln. 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Dickinson device to include a filter with framework, as taught by Kurashima, in order to provide structural support to the filter and to keep the filter from becoming dislodged. The now modified Dickinson device is silent as to a means to lock the filter in place in the inlet explicitly being a friction fit. However, friction fitting components of a respiratory device is well-known in the art and furthermore, Fukunaga teaches friction fitting components of a respiratory device (see Fukunaga para. 0060 ln. 48-50 and para. 0097 ln. 9). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Dickinson device's filter to be locked in place using friction fitting locking means, as taught by Fukunaga, as this type of locking mechanism is well-known in the art and to provide a to provide a mechanism such that the filter does not become dislodged.

In regards to claim 9, the modified Dickinson device's filter material (Kurashima 15) is disposed between the structural members of the frame work (see Fig. 1-6 of Kurashima).

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-4 and 15-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 7,111,624 to Thudor et al. in view of Lipscombe et al. (6,554,260) and Clawson et al. (6,363,930).

In regards to application claims 1-2 and 15-16, claim 1 of the U.S. Patent 7,111,624 (referred to as Thudor '624) while not using identical claim language, discloses an apparatus for use in humidified gases delivery with a housing, pressurized gases supply, outlet in fluid connection with gases supply adapted to make fluid connection with an inlet of a humidifier to provide pressurized gases flow to the humidifier (see Thudor '624 claim 1), humidified gases return in the housing to make connection with humidifier outlet and a patient outlet in the housing to make fluid connection with breathing conduit for delivery of humidified gases to the patient. The Thudor '624 claim 1 device is silent as to including a filter in the gases inlet of the humidifier and downstream of the pressurized gases supply. However, Lipscombe teaches a CPAP humidifier device which includes a filter in the gases inlet of a humidifier and downstream of a pressurized gases supply (see Lipscombe col. 4 ln. 27-31). It would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the Thudor '624 claim 1 device to include a filter in the gases inlet of the humidifier and downstream of the pressurized gases supply, as taught by Lipscombe, in order to reduce the presence of bacteria in the device. The now modified Thudor '624 claim 1 device is silent as to the filter being removable; however, Clawson teaches a breathing device which includes a removable filter (see Clawson col. 2 ln. 56-59). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Thudor '624 claim 1 device's filter to be removable, as taught by Clawson, in order to ensure the filter is functioning properly and to replace the filter when necessary to prevent contamination. The modified Thudor '624 claim 1 device includes a filter positioned to protect the pressurized gases supply, housing and humidifier from contamination.

In regards to application claim 3, claim 2 of modified Thudor '624, as modified above, teaches a humidifier with a heatable water chamber, chamber heating means, and a humidifier engagement as claimed (see claim 2 of Thudor '624).

In regards to application claim 4, claim 3 of modified Thudor '624, as modified above, teaches a humidification chamber with a base and an engagement single motion as claimed such that all fluid connections are made in the single engagement motion.

15. Claim 5 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,111,624 to Thudor in view of Lipscombe et al. (6,554,260), Clawson et al. (6,363,930) and Blackhurst (WO 02/32486).

In regards to application claim 5, claim 1 of modified Thudor '624, as modified above in rejection of application claim 2, is silent as to a patient outlet including a connector for receiving a breathing hose **and** at least one auxiliary electrical connection plug or socket or pneumatic connection plug or port, for a simultaneous connection with connecting a breathing circuit having complementary electrical and pneumatic connectors. However, Blackhurst teaches a breathing house with a connector (3 see Blackhurst Fig. 2) which also includes at least one auxiliary electrical connection plug or socket (Blackhurst Fig. 2 via connection 21 see also pg. 9 ln. 6-7) **or** pneumatic connection plug or port, for a simultaneous connection when connecting a breathing circuit having complementary electrical and pneumatic connectors (see Blackhurst Fig. 2; note that the breathing conduit and electrical connection are both connected simultaneously). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Thudor '624 claim 1 device to include the auxiliary electrical connection plug as claimed as taught by Blackhurst in order to provide the ability to further heat the gas via a breathing conduit heater element for example in order to maintain proper temperature and humidity level of the breathing gas being supplied to the patient.

16. Claims 17-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,111,624 to Thudor in view of Lipscombe et al. (6,554,260), Clawson et al. (6,363,930) and Hoffrichter (DE 10226160).

In regards to application claims 17, claim 1 of modified Thudor '624, as modified above in rejection of application claim 1, is silent as to the humidification chamber being a water chamber with the removable filter being attached inside the water chamber. However, Hoffrichter teaches a humidifier device which includes a water chamber with inlet/outlet tubes extending into the water chamber (see Hoffrichter Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Thudor '624 claim 1 device's humidifier inlet/outlets to extend into a water chamber, as taught by Hoffrichter, in order to provide a smaller, more compact device. The now modified Thudor '624 claim 1 device teaches a humidifier water chamber with gases inlet extending into the chamber (see Hoffrichter Fig. 1) and a filter in the humidifier inlet (see Lipscombe col. 4 ln. 28-31), and it would have been obvious to one of ordinary skill in the art at the time the invention was made to place the filter such that it is inside the water chamber (humidifier gases inlet includes the filter and inlet as shown in Fig. 1 of Hoffrichter extends into the water chamber).

In regards to application claim 18, claim 1 of modified Thudor '624, as modified above in rejection of application claim 1, includes a humidifier with a water chamber (see Fig. 1 of Hoffrichter) and the removable filter and water chamber are detachable from the pressurized gases supply together (removable filter Lipscombe col. 4 ln. 28-31, and Hoffrichter Fig. 1).

17. Claims 1-7, 11-12 and 15-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

claims 2, 6, 7, 8, 10, and 11 of copending Application No. 11/428704 to Thudor in view of Lipscombe et al. (6,554,260) and Clawson et al. (6,363,930).

This is a provisional obviousness-type double patenting rejection.

See attached copy of most recent amended claims for 11/428704 which are used in the following rejections.

In regards to application claims 1-2 and 15-16, claim 2 of application 11/428704 to Thudor (referred to as Thudor '704) while not using identical claim language, discloses an apparatus for use in humidified gases delivery with a housing, pressurized gases supply, outlet in fluid connection with gases supply adapted to make fluid connection with an inlet of a humidifier to provide pressurized gases flow to the humidifier (see Thudor '704 claims 1-2), humidified gases return in the housing to make connection with humidifier outlet and a patient outlet in the housing to make fluid connection with breathing conduit for delivery of humidified gases to the patient. The Thudor '704 claim 2 device is silent as to including a filter in the gases inlet of the humidifier and downstream of the pressurized gases supply. However, Lipscombe teaches a CPAP humidifier device which includes a filter in the gases inlet of a humidifier and downstream of a pressurized gases supply (see Lipscombe col. 4 ln. 27-31). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Thudor '704 claim 2 device to include a filter in the gases inlet of the humidifier and downstream of the pressurized gases supply, as taught by Lipscombe, in order to reduce the presence of bacteria in the device. The now modified Thudor '704 claim 2 device is silent as to the filter being removable; however,

Clawson teaches a breathing device which includes a removable filter (see Clawson col. 2 ln. 56-59). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Thudor '704 claim 2 device's filter to be removable, as taught by Clawson, in order to ensure the filter is functioning properly and to replace the filter when necessary to prevent contamination. The modified Thudor '704 claim 2 device includes a filter positioned to protect the pressurized gases supply, housing and humidifier from contamination.

In regards to application claim 3, claim 2 of modified Thudor '704, as modified above, teaches a humidifier with a heatable water chamber, chamber heating means, and a humidifier engagement as claimed (see claim 2 of Thudor '704).

In regards to application claim 4, claim 2 of modified Thudor '704, as modified above, teaches a humidification chamber with a base and an engagement single motion as claimed such that all fluid connections are made in the single engagement motion.

In regards to application claim 5, claim 6 of modified Thudor '704, as modified above, teaches a patient outlet with connector and at least one auxiliary connection plug/socket or pneumatic connection plug/port as claimed (see Thudor '704 claim 6).

In regards to application claim 6, claim 7 of modified Thudor '704, as modified above, teaches a humidifier chamber with container wall, top, open bottom, heat conductive base, gases inlet, and gases outlet as claimed (see Thudor '704 claim 7) as well as a removable filter as claimed (see Lipscombe and Clawson references as applied above).

In regards to application claim 7, claim 10 of modified Thudor '704, as modified above, teaches a humidification chamber with parallel first and second elongate flow tubes as claimed (see Thudor '704 claim 10).

In regards to application claim 11, claim 11 of modified Thudor '704, as modified above, teaches an air bleed orifice as claimed (see Thudor '704 claim 11).

In regards to application claim 12, claim 8 of modified Thudor '704, as modified above, teaches gases inlet/outlet are female port with a generally cylindrical humidifier chamber as claimed (see Thudor '704 claim 8).

18. Claims 17-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of copending Application No. 11/428704 to Thudor in view of Lipscombe et al. (6,554,260), Clawson et al. (6,363,930) and Hoffrichter (DE 10226160).

This is a provisional obviousness-type double patenting rejection.

In regards to application claims 17, claim 2 of modified Thudor '704, as modified above in rejection of application claim 1, is silent as to the humidification chamber being a water chamber with the removable filter being attached inside the water chamber. However, Hoffrichter teaches a humidifier device which includes a water chamber with inlet/outlet tubes extending into the water chamber (see Hoffrichter Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Thudor '704 claim 2 device's humidifier inlet/outlets to extend into a water chamber, as taught by Hoffrichter, in order to provide a smaller, more compact

device. The now modified Thudor '704 claim 2 device teaches a humidifier water chamber with gases inlet extending into the chamber (see Hoffrichter Fig. 1) and a filter in the humidifier inlet (see Lipscombe col. 4 ln. 28-31), and it would have been obvious to one of ordinary skill in the art at the time the invention was made to place the filter such that it is inside the water chamber (humidifier gases inlet includes the filter and inlet as shown in Fig. 1 of Hoffrichter extends into the water chamber).

In regards to application claim 18, claim 2 of modified Thudor '704, as modified above in rejection of application claim 1, includes a humidifier with a water chamber (see Fig. 1 of Hoffrichter) and the removable filter and water chamber are detachable from the pressurized gases supply together (removable filter Lipscombe col. 4 ln. 28-31, and Hoffrichter Fig. 1).

19. Claims 8-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of copending Application No. 11/428704 in view of Lipscombe et al. (6,554,260), Clawson et al. (6,363,930), Kurashima (6,033,455) and Fukunaga et al. (2002/0017302).

This is a provisional obviousness-type double patenting rejection.

In regards to application claims 8 and 10, claim 7 of modified Thudor '704, as modified above in rejection of application claim 6, is silent as to the filter including a framework and friction fit locking means as claimed. However, Kurashima teaches a filter which includes a framework (Kurashima 1 and 2 see Fig. 3 for example) supporting

a filter material (Kurashima 15 see Fig. 3 for example) where the framework is shaped to fit the internal shape of the inlet (see Kurashima Fig. 1 and 6 for example; note that inlet/outlets of the framework are sized to fit with a breathing conduit; see also Kurashima col. 6 ln. 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Thudor '704 claim 7 device to include a filter with framework, as taught by Kurashima, in order to provide structural support to the filter and to keep the filter from becoming dislodged. The now modified Thudor '704 claim 7 device is silent as to a means to lock the filter in place in the inlet explicitly being a friction fit. However, friction fitting components of a respiratory device is well-known in the art and furthermore, Fukunaga teaches friction fitting components of a respiratory device (see Fukunaga para. 0060 ln. 48-50 and para. 0097 ln. 9). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Thudor '704 claim 7 device's filter to be locked in place using friction fitting locking means, as taught by Fukunaga, as this type of locking mechanism is well-known in the art and to provide a to provide a mechanism such that the filter does not become dislodged.

In regards to application claim 9, claim 7 of modified Thudor '704, as modified above, includes filter material (Kurashima 15) disposed between the structural members of the frame work (see Fig. 1-6 of Kurashima).

Response to Arguments

20. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN W. STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-Thr 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN W STUART/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

